(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 198 843 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication of patent specification: **01.04.92**

(51) Int. Cl.5: **B32B 27/08**, A61B 19/00

(21) Application number: **85904554.4**

(22) Date of filing: **06.09.85**

(86) International application number:
PCT/US85/01691

(87) International publication number:
WO 86/02042 (10.04.86 86/08)

(54) FILM LAMINATE WITH GAS BARRIER FOR STERILE FLEXIBLE CONTAINERS.

(30) Priority: **28.09.84 US 655493**

(43) Date of publication of application:
29.10.86 Bulletin 86/44

(45) Publication of the grant of the patent:
01.04.92 Bulletin 92/14

(84) Designated Contracting States:
BE CH DE FR GB IT LI NL SE

(56) References cited:
GB-A- 2 029 762
US-A- 3 514 367
US-A- 3 912 843
US-A- 4 461 808
US-A- 3 297 518
US-A- 3 908 070
US-A- 4 407 873

(73) Proprietor: **FUJIMORI KOGYO CO., LTD.**
Daiichi Building 4-16, Nihonbashi Bakuro-cho 1-chome Chuo-ku
Tokyo 103(JP)

Proprietor: **BAXTER INTERNATIONAL INC. (a Delaware corporation)**
One Baxter Parkway
Deerfield Illinois 60015(US)

(72) Inventor: **JOHNSTON, William, D.**
801 Dannet
Buffalo Grove, IL 60090(US)
Inventor: **CZUBA, Leonard**
437 S. Lombard
Lombard, IL 60148(US)
Inventor: **WEBSTER, R., D.**
830 Hillside
Barrington, IL 60010(US)
Inventor: **HORI, Yasuhiko**
3740-7, Nogawa
Takatu-ku Kawasaki 213(JP)
Inventor: **NAGATA, Masanori**
3-16-40, Nishi-Oi
Shinagawa-ku Tokyo 140(JP)
Inventor: **IMANO, Shigeki**
2-9-20, Oda
Kawasaki-ku Kawasaki 210(JP)

EP 0 198 843 B1

(74) Representative: MacGregor, Gordon et al
ERIC POTTER & CLARKSON St. Mary's Court
St. Mary's Gate
Nottingham, NG1 1LE(GB)

Description

This invention relates to a film laminate structure for flexible containers. In particular, this invention relates to a multi layer high barrier laminate film structure for flexible containers capable of containing a product to be maintained and removed under sterile conditions.

Flexible containers are utilized in the medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma. Because these containers are utilized to contain fluids or solids that are introduced into a patient's body, it is necessary for the containers to be: essentially transparent; flexible; essentially free of extractables; and capable of maintaining the product contained therein under sterile conditions until the product is accessed or removed from the flexible container.

It is also important that the film used in constructing these containers is sufficiently strong so that the containers constructed from the film have sufficient strength. Moreover, if the laminate film is to be constructed into a commercially viable flexible container, it is necessary that the flexible film can be run on some type of commercial production machine. One such machine is a form, fill and seal packaging machine. A form, fill and seal packaging machine requires that the film be sealable on at least two sides. The side seals are typically effectuated by sealing the inside layer of the film to itself.

It is desirable to attach a fitment on the film structure to create a flexible container with a fitment. The fitment is typically heat sealed to the film. Accordingly, it is necessary that the film structure is heat sealable on its outside layer so that the fitment may be sealed thereto.

Because the film laminate is to be utilized for flexible containers that house a medical product that is to be introduced into a patient's body, it is necessary that the film structure does not contain chemicals that will be extracted by the medical product. This is an especially critical consideration when choosing an adhesive for bonding the laminate layers together. If a fitment is utilized and sealed to the outside layer of the film it is possible that there will be fluid communication between the product and the layers of the laminate. Thus, if the adhesive contains possible hazardous components that may be extractable the film may not include a fitment sealed to the outside wall.

A further consideration in choosing the proper film for creating a flexible container is the product to be housed. In applications of the film to produce containers for products stored at room temperature, it is necessary that the film provides a container with sufficient barrier properties. Without a sufficient barrier, water vapor, oxygen, and other gases and vapors may permeate the film inactivating or degrading the product contained therein.

Thus, there is a need for a film laminate structure for creating a sterile flexible container that overcomes the disadvantages of the prior art.

US-A-3 514 367 discloses a laminate film structure for wrapping food products, such as meats and cheeses, the film structure comprising a polyamide substrate coated with a polyurethane primer and a gas barrier layer and adhered to a polyethylene film. The pre-characterising part of Claim 1 is based on this disclosure.

The distinguishing features of the invention are as set out in the characterising part of Claim 1.

The polyurethane adhesive layers preferably have a thickness of 1 to 10 µm. The preferred thickness of the film laminate is 155 to 230 µm. Preferably the inside and outside layers have a density of .91 to .94 grams/cubic centimeters.

In a preferred embodiment the film laminate can be formed into, and function as a container for products maintained at room temperature. The preferred material for the gas barrier is polyvinylidene chloride.

The outside and inside polyethylene layers of the film laminate preferably include an antioxidant, stabilizer, antiblocking agent, and slip agent.

Accordingly, it is an advantage of the present invention to provide a multilayer laminate structure that may be utilized to create a sterile flexible container, is sealable on its inside and outside layers, and can be utilized to produce a container having a fitment heat sealed on the outside wall.

Moreover, an advantage of the present invention is to provide a film laminate structure that can be utilized to produce a flexible bag that may house parenteral products including intravenous solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma.

A further advantage of the present invention is to create a film laminate structure that can be utilized in a form, fill and seal packaging machine to create a flexible container.

A still further advantage of the present invention is that it provides a film that can be utilized to produce flexible containers for housing drugs and products maintained at temperatures above 0 °C.

Additional features and advantages are described in, and will be apparent from, the Detailed Description of the Presently Preferred Embodiments and from the drawings.

Figure 1 illustrates a schematic cross-sectional view of an embodiment of the film laminate structure of this invention.

Figure 2 illustrates a perspective view of a flexible container constructed from the film lami-

nate of this invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The film structure of the present invention is utilized to produce flexible containers capable of containing a fluid or solid to be maintained and removed under sterile conditions. These containers typically consist of a liquid containment body defined by thermally sealed walls. The containers are utilized to package, inter alia, parenteral products including intravenous solutions, dialysis solutions, frozen drugs, nutrition products, respiratory therapy products, and plasma. The preferred film structure of this invention is a multilayer laminate structure designed to package parenteral products including intravenous solutions, dialysis solutions, nutrition products, respiratory therapy products, and plasma.

Referring to Figure 1, a presently preferred embodiment of the film laminate structure 10 of the present invention is illustrated. The film laminate structure 10 includes an outside layer 12, a first adhesive layer 14, a gas barrier 16, a second adhesive layer 18, a core layer 20, a third adhesive layer 22, and an inside layer 24. As will be described in more detail below, the adhesive layers 14, 18 and 22 bond the outside and gas barrier layers 12 and 16, the gas barrier and core layers 16 and 20, and the core and inside layers 20 and 24 respectively. As also discussed in more detail below, as illustrated in Figure 2, the film laminate structure 10 may be utilized to create a flexible container.

The outside and inside layers 12 and 24 are constructed from a polyethylene polymer. Preferably, the outside and inside layers 12 and 24 are a linear low density polyethylene. As used herein, linear low density means that the polyethylene is made by low pressure polymerization and has a density between approximately .91 to about .94 grams/cubic centimeter. The preferred density of the linear polyethylene is .915 to .93 grams/cubic centimeter.

The preferred linear low density polyethylene contains 2% to 10% by weight 1-hexene. In a most preferred embodiment, the polyethylene copolymer contains approximately 5% by weight 1-hexene. Other olefinic comonomers with 4 to 18 carbon atoms also function satisfactorily. Examples of these olefins are 1-octene, 1-butene, 1-pentene, and 4-methyl-1-pentene which may be present as 5% to 11% by weight of the linear low density polyethylene.

Because the film laminate 10 is to be utilized to produce flexible containers through a commercial packaging machine, it is important that the outside layer 12 has a sufficiently low coefficient of friction. The outside layer 12 must have a low coefficient of friction to ensure that it flows smoothly through the processing machine, e.g., a form, fill and seal packaging machine. Preferably the outside layer 12 has a coefficient of friction of .2 to .4 as measured by ASTM test D-1894 between the outside layer and a stainless steel surface. The preferred coefficient of friction of the outside layer 12 is approximately .25.

To provide the linear low density polyethylene with a sufficiently low coefficient of friction the polyethylene copolymer is slip modified by adding a fatty acid amide additive that acts like a lubricant and lowers the coefficient of friction of the film 10. The preferred fatty acid amides have 8 to 22 carbon atoms. Oleic amide has been found to modify the linear low density polyethylene sufficiently to produce the required coefficient of friction. Preferably .03% to .15% by weight of oleic amide is added to the linear low density polyethylene.

An important consideration for the outside layer 12 and inside layer 24 is their thickness. In order to create a flexible container the inside layer 24 must be sealed to itself on at least two walls 28 and 30. Moreover fitment 32 is heat sealed to the outside layer 12. Preferably, the outside layer 12 and inside layer 24 have a thickness of 40 to 100 µm. The preferred thickness of the outside and inside layers 12 and 24 is between 50 and 70 µm. This thickness affords: a good heat seal; good clarity; pinhole resistance; a good tensile strength; sufficient impact strength; and provides good flexibility for the film laminate 10.

It is not necessary that the outside layer 12 and inside layer 24 have the same thickness. However, if the outside layer 12 and inside layer 24 have the same thickness, and the layers have approximately the same coefficient of friction, this provides a film structure that resists curl and is a more versatile film laminate 10 in that it may be fed into the packaging machine with either side facing in either direction.

The linear low density polyethylene layers 12 and 24 provide properties to the film laminate structure 10 that allows the laminate to be utilized to produce a frozen drug bag. The low temperature properties, as well as the excellent heat sealability of linear low density polyethylene makes it suitable for use in producing a frozen drug bag. These properties are important in view of the fact that the temperature of the frozen drug bag when it is shipped is -25 °C. For typical prior art flexible containers, e.g., those made from polyvinyl chloride, at this temperature the containers fall below the glass transition state, and therefore the materials of which the containers are made are very brittle. Therefore, flexible bags made from polyvinyl chlo-

ride may easily break. In contrast, linear low density polyethylene's glass transition state is below -80°C and accordingly, when used as a frozen drug bag it will not fall below its glass transition state.

Preferably, the outside layer and inside layer 12 and 24 contain an antioxidant. The antioxidant functions to provide needed properties when the resin pellets are produced. Four antioxidants have been found to provide satisfactory results: tetrakis-[methylene-3-(3',5'-di-tert-butyl-4'-hydroxy phenyl) propionate] methane (manufactured by Ciba-Geigy under the name Irganox 1010); n-octadecyl-beta-(4'-hydroxy-3', 5'-di-tert-butyl phenyl) propionate (manufactured by Ciba-Geigy under the name Irganox 1076); butylated hydroxytoluene; 1,3,5-trimethyl-2,4,6-tris[3,5-di-tert-butyl-4-hydroxybenzyl] benzene ("Ethyl" antioxidant 330 manufactured by Ethyl Corporation); and tetrakis-(2,4-di-tert-butylphenyl)-4-4'- biphenylene diphosphate (manufactured by Sandoz under the name Sandostab P-EPQ). The preferred antioxidants are Irganox 1010 and P-EPQ. Preferably approximately .03% to about .15% by weight of the antioxidant are added to the linear low density polyethylene copolymer.

The linear low density polyethylene preferably also contains a stabilizer and an antiblocking agent. The stabilizer provides needed properties during the production of the film from the resin pellets. Preferably the stabilizer is calcium stearate and comprises .02% to .06% by weight of the polyethylene. The antiblocking agent prevents the film from sticking together. Preferably the antiblocking agent is magnesium silicate and comprises .11% to .15% by weight. Other antiblocking agents that have been found to produce satisfactory results are aluminum hydroxide and magnesium hydroxide.

The gas barrier layer 16 of the film laminate 10 functions to provide a high barrier laminate. Because of the gas barrier layer 16 the film laminate 10 is highly impermeable to water, oxygen, and other fluids. This allows the film laminate 10 to be utilized to create flexible containers 30 that can house drugs and other products that are maintained or stored at temperatures above 0°C. Specifically, the film laminate 10 can be utilized to create flexible containers for housing medical products stored at room temperature.

The preferred material for the gas barrier is polyvinylidene chloride (PVDC) manufactured by Dow Chemical and sold under the trademark SARAN. Dow Chemical's PVDC film X01621.10 has been found to produce satisfactory results as has a PVDC film manufactured by Asahi Kasei Kogyo Co., of Japan. The gas barrier may also be constructed from a hydrolized ethylene vinyl acetate.

Preferably the gas barrier has a thickness of 18 to 60 µm. Most preferably, the gas barrier has a thickness of 25 to 50 µm.

The core layer 20 of the present invention is a polyamide, preferably nylon. The preferred nylon for the core layer 20 is a biaxially oriented nylon. A biaxially oriented nylon 6, such as the one manufactured by Unitika Ltd. of Osaka, Japan has been found to produce satisfactory results. Other nylons may also be utilized. Examples of such nylons are nylon 6-6, nylon 11, and nylon 12. All of these nylons are biaxially oriented.

As used herein, biaxially oriented nylon means that the nylon film has been extruded and stretched in both directions. This ensures that the molecules of nylon are biaxially oriented. This provides the film laminate structure 10 with increased mechanical qualities, i.e. pinhole resistance; tear resistance (resistance to the start of a tear); and stretch resistance.

Preferably, the core layer 20 has a thickness of between 10 to 40 µm. The preferred thickness of the core layer 20 is approximately 15 to about 20 µm. Preferably, the biaxially oriented nylon includes a slip agent. The preferred slip agent is silicon dioxide.

The first adhesive layer 14 bonds the outside layer 12 to the gas barrier layer 16, the second adhesive layer 18 bonds the gas barrier layer 16 to the core layer 20; and the third adhesive layer 22 bonds the inside layer 24 and core layer 20 to each other. Preferably the adhesive is an aliphatic polyurethane. The preferred aliphatic polyurethane is a polyester-urethanediol resin manufactured by Takeda Chemical Industries Co., Ltd. under the name Takelac A-385 or Takelac A-520. The preferred aliphatic polyurethane sealer layers 14, 18 and 22 also include a hardener, Takenate A-50 manufactured by Takeda Chemical Industries Co., Ltd., comprising 3-isocyanatomethyl-3,5, 5-trimethyl cyclohexyl isocyanate adduct trimethylol propane or 1,3-bis (isocyanatomethyl) benzene adduct of trimethylol propane, and a solvent ethyl acetate.

The adhesive layers 14, 18 and 22 create a strong bond between the polyethylene layers 12 and 24, the gas barrier layer 16, and the core layer 20. Preferably the peel strength of the bond is at least 500 gms/inch 1.93 N/cm of force to delaminate. The aliphatic polyurethane adhesive layers 14, 18 and 22 also provide the following desirable properties to the laminate film structure 10: transparency; flexibility; low temperature resistance; processability; initial tackiness; and pinhole resistance.

The preferred thickness of each of the adhesive layers 14 18 and 22 is 1 to 10 µm. The most preferred thickness of each of the adhesive layers 14, 18 and 22 is 3 to 5 µm.

It has been found that the adhesive layers 14, 18 and 22 may be utilized even when a fitment 32 is attached to the outside layer 12. When the fitment 32 is attached to the outside layer 12, the product within the container will be in fluid communication with the adhesive layers 14, 18 and 22.

The total thickness of the film laminate 10 is preferably 155 to 230 µm. This provides a film laminate that: is flexible; has good strength; has good heat seals; good clarity; and sufficient impact strength.

The film laminate 10 of this invention is preferably produced by dry lamination. Preferably, a dry lamination process utilizing a two-component curing system is utilized. The adhesive is tacky at the time of combination, and curing occurs at a controlled temperature.

Referring now to Figure 2, the flexible container constructed from the film laminate 10 of this invention is illustrated. As illustrated, the inside layer 24 is heat sealed together on itself to create walls 28, 30 and 34. Due to the construction of the inside layer 24, a strong heat seal is created.

Also, as illustrated, a fitment 32 may be sealed to the outside layer 12 of the container. Preferably, the fitment 32 is heat sealed to the outside layer 12. Due to the construction of the outside layer 12, a strong heat seal is created.

Thus, the present invention creates a film laminate structure 10 that can run through a form, fill and seal packaging machine to create flexible containers including a fitment 32 that can house a medical product to be maintained and extracted under sterile conditions.

By way of example, and not limitation, examples of the film laminate 10 will now be set-forth:

EXAMPLE 1

Step 1

Laminate a 25 µm film of Dow PVDC film X01621.10 to a 15 µm film of oriented nylon 6 polymer (the nylon 6 includes a silicon dioxide as a slip agent) using 3-4 µm of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 2

Laminate a 60 µm blown film of linear low density polyethylene (the polyethylene has 5% by weight 1-hexene as its copolymer component and the following additives: antioxidants-Irganox 1010 and P-EPQ, stabilizer-calcium stearate, antiblock-magnesium silicate and slip agent-oleic amide) to the laminate made in Step 1 using 3-4 µm of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 3

Take the three layer laminate made in Step 2 and using the same dry bonding lamination process, laminate another 60 µm layer of the same polyethylene mentioned above to the other side of the laminate film. In each step, the adhesive is applied to the laminate film and "dried" before combining with the polyethylene.

Step 4

The four layer laminate is then cured in a controlled temperature environment such as an oven to completely cure the adhesive layers and allow full bonding of the layers.

EXAMPLE 2

Step 1

Laminate a 50 µm film of Dow PVDC film X01621.10 to a 15 µm film of oriented nylon 6 polymer (the nylon 6 includes a silicon dioxide as a slip agent) using 3-4 µm of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 2

Laminate a 60 µm blown film of linear low density polyethylene (the polyethylene has 5% by weight 1-hexene as its copolymer component and the following additives: antioxidants-Irganox 1010 and P-EPQ, stabilizer-calcium stearate, antiblock-magnesium silicate and slip agent-oleic amide) to the laminate made in Step 1 using 3-4 µm of an aliphatic urethane adhesive by way of a dry-bonding process.

Step 3

Take the three layer laminate made in Step 2 and using the same dry bonding lamination process, laminate another 60 µm layer of the same polyethylene mentioned above to the other side of the laminate film. In each step, the adhesive is applied to the laminate film and "dried" before combining with the polyethylene.

Step 4

The four layer laminate is then cured in a controlled temperature environment such as an oven to completely cure the adhesive layers and allow full bonding of the layers.

Claims

1. A laminate film structure comprising a polyamide core layer (20), a gas barrier layer (16) adhered to the core layer by a polyurethane adhesive layer (18), and a first polyethylene layer (24) adhered to one of said previous layers (20) characterised:-

   by a second polyethylene layer (12) adhered to the other of said previous layers (16);

   in that the polyethylene layers (12,24) are adhered to the said previous layers (16,20) by polyurethane adhesive;

   in that each polyethylene layer (12,24) has a thickness of 40 to 100 µm;

   in that at least one (12) of the polyethylene layers, for forming the outer layer of a container, includes a slip agent and has a coefficient of friction of 0.2 to 0.4;

   in that the core layer (20) comprises biaxially oriented polyamide having a thickness of 10 to 40 µm;

   in that the gas barrier layer (16) has a thickness of 25 to 50 µm,

   and in that the polyurethane adhesive is an aliphatic polyurethane;

   the film structure having sufficient flexibility, strength, heat sealability and slip properties for producing by heat-sealing on a packaging machine flexible containers having fitments attached thereto and capable of containing liquid under sterile conditions.

2. The film structure of Claim 1 wherein the gas barrier layer (16) is a polyvinylidene chloride.

3. The film structure of Claim 1 or 2 wherein the polyethylene is a linear low density polyethylene.

4. The film structure of Claim 3 wherein the density of the linear low density polyethylene layers is .91 to .94 g/cm^3.

5. The film structure of Claim 3 or 4 wherein the linear low density polyethylene layers include the following additives:

   an antioxidant;

   a stabilizer;

   a slip agent; and

   an antiblocking agent.

6. The film structure of Claim 5 wherein:

   the antioxidant is tetrakis[methylene-3-(3'5'-di-tert-butyl-4'-hydroxy phenyl) propionate] methane, n-octadecyl-beta-(4'-hydroxy-3',5'-di-tert-butylphenyl) propionate, butylated hydroxytoluene, tetrakis (2,4-di-tert-butylphenyl)-4,4'-biphenylene disphosphonite, or 1,3,5 trimethyl-2,4,6-tris[3,5-di-tert-butyl-4-hydroxybenzyl]benzene;

   the stabilizer is calcium stearate; and

   the antiblocking agent is magnesium hydroxide, aluminium hydroxide, or magnesium silicate.

7. The film structure of any preceding claim wherein the polyethylene contains 2% to 10% by weight 1-hexene as comonomer.

8. The film structure of any preceding Claim wherein the aliphatic polyurethane adhesive has a thickness of 1 to 10 µm.

9. The film structure of Claim 8 wherein the polyurethane adhesive comprises a polyesterurethanediol resin.

10. The film structure of any preceding claim wherein the bond strength of the polyethylene layers (12,24) to the gas barrier layer (16) and core layer (20) is at least 500 gms/inch (1.93 N/cm) of force to delaminate.

11. The film structure of any preceding Claim wherein the thickness of the film structure is 155 to 230 µm.

12. The film structure of any preceding Claim wherein the second polyethylene layer (12) includes .03% to .15% by weight of a fatty acid amide containing 8 to 22 carbon atoms.

13. The film structure of Claim 12 wherein the fatty acid amide is an oleic amide.

14. A flexible container capable of containing under sterile conditions a fluid or solid to be stored at temperatures above 0°C having a body with opposed, peripherally sealed walls forming the container, the walls being constructed from a film structure according to any of Claims 1 to 13, with portions of one polyethylene layer (24) being heat sealed together to create the walls of the flexible container and with a fitment (32) heat sealed to the body.

15. A flexible container containing under sterile conditions a medical liquid at temperatures above 0°C, or a frozen medical liquid the container having a body heat-sealed from a film structure and having a fitment heat-sealed to the body, the film structure not containing chemicals that are extractable by the liquid and having a glass transition state below -25°C, the film structure being as claimed in any one of Claims 1 to 13.

Revendicati ns

1. Structure de laminé pelliculaire comprenant une couche centrale de polyamide (20), une couche antigaz (16) collée à la couche centrale par une couche de colle de polyuréthane (18) et une première couche de polyéthylène (24) collée à l'une desdites couches précédentes (20, caractérisée

   par une deuxième couche de polyéthylène (12) collée à l'autre desdites couches précédentes (16);

   par le fait que les couches de polyéthylène (12, 24) sont collées auxdites couches précédentes (16, 20) par une colle au polyuréthane;

   par le fait que chaque couche de polyéthylène (12, 24) a une épaisseur comprise entre 40 et 100 µm;

   par le fait qu'au moins l'une (12) des couches de polyéthylène destinées à former la couche extérieure d'un récipient contient un agent de glissement et un coefficient de frottement compris entre 0,2 et 0,4;

   par le fait que la couche centrale (20) comprend un polyamide à orientation biaxiale ayant une épaisseur de 10 à 40 µm;

   par le fait que la couche antigaz (16) a une épaisseur comprise entre 25 et 50 µm,

   et par le fait que la colle de polyuréthane est un polyuréthane aliphatique;

   la structure du film ayant une flexibilité, une résistance, une aptitude au soudage à chaud et des propriétés de glissement suffisantes pour la fabrication par scellement à chaud dans une machine à emballer de récipients flexibles ayant des accessoires fixés à ceux-ci et capables de contenir des liquides dans des conditions stériles.

2. Structure de film selon la revendication 1, dans laquelle la couche antigaz (16) est du chlorure de polyvinylidène.

3. Structure de film selon la revendication 1 ou 2, dans laquelle le polyéthylène est du polyéthylène linéaire à basse densité.

4. Structure de film selon la revendication 3, dans laquelle le poids spécifique des couches de polyéthylène linéaire à basse densité est compris entre 0,91 et 0,94 g/cm^3.

5. Structure de film selon la revendication 3 ou 4, dans laquelle les couches de polyéthylène linéaire à basse densité comprennent les additifs suivants :

   un antioxydant,
   un stabilisant,
   un agent de glissement, et
   un agent antiblocage.

6. Structure de film selon la revendication 5, dans laquelle

   l'antioxydant est du tétrakis[méthylène 3-(3',5'-di-tert-butyl-4'-hydroxyphényl)-propionate] méthane, du n-octadécyl-β-(4'-hydroxy-3', 5'-di-tert-butylphényl)propionate, de l'hydroxytoluène butylé, du tétrakis(2,4-di-tert-butylphényl)-4,4'-biphénylène di-phosphonite ou du 1,3,5-triméthyl-2,4,6-tris[3,5-di-tert-butyl-4-hydroxybenzyl]benzène,

   le stabilisant est du stéarate de calcium,et

   l'agent antiblocage est de l'hydroxyde de magnésium, de l'hydroxyde d'aluminium ou du silicate de magnésium.

7. Structure de film selon l'une quelconque des revendications précédentes, dans laquelle le polyéthylène contient de 2 à 10% en poids de 1-hexène comme monomère.

8. Structure de film selon l'une quelconque des revendications précédentes, dans laquelle la colle de polyuréthane aliphatique a une épaisseur de 1 à 10 µm.

9. Structure de film selon la revendication 8, dans laquelle la colle de polyuréthane comprend une résine de polyester-uréthanediol.

10. Structure de film selon l'une quelconque des revendications précédentes, dans laquelle la résistance de l'assemblage des couches de polyéthylène (12, 24) à la couche antigaz (16) et à la couche centrale (20) est d'au moins 500 g/pouce (1,93 N/cm) comme force pour séparer le laminé.

11. Structure de film selon l'une quelconque des revendications précédentes, dans laquelle l'épaisseur de la structure de film est comprise entre 155 et 230 µm.

12. Structure de film selon l'une quelconque des revendications précédentes, dans laquelle la deuxième couche de polyéthylène (12) contient de 0,03 à 0,15% en poids d'un amide d'acide gras ayant de 8 à 22 atomes de carbone.

13. Structure de film selon la revendication 11, dans laquelle l'amide d'acide gras est un amide oléique.

14. Récipient flexible pouvant contenir, dans des

conditions stériles, un fluide ou un solide à stocker à des températures supérieures à 0 °C, ayant une structure avec des parois opposées scellées à la périphérie formant le récipient, les parois étant constituées d'une structure de film selon l'une quelconque des revendications 1 à 12, avec des parties d'une couche de polyéthylène (24) assemblées l'une à l'autre par soudage à chaud afin de créer les parois du récipient flexible et avec un accessoire (32) soudé à chaud à cet assemblage.

15. Récipient flexible contenant, dans des conditions stériles, un liquide médical à des températures supérieures à 0 °C ou un liquide médical congelé, le récipient ayant une structure assemblée par soudage à chaud réalisée avec une structure de film et ayant un accessoire fixé par soudage à chaud à sa structure, la structure de film ne contenant pas de produits chimiques pouvant être extraits par le liquide et ayant un état de transition vitreux inférieur à -25 °C, la structure du film étant conforme à l'une quelconque des revendications 1 à 13.

Patentansprüche

1. Verbundschichtstruktur, die aufweist: eine Polyamidkernschicht (20), eine Gassperrschicht (16), die durch eine Polyurethan-Haftschicht (18) an der Kernschicht haftet, und eine erste Polyethylenschicht (24), die an einer (20) der vorhergehenden Schichten haftet, gekennzeichnet:

   durch eine zweite Polyethylenschicht (12), die an der anderen (16) der vorhergehenden Schichten haftet; und dadurch:

   daß die Polyethylenschichten (12, 24) durch einen Polyurethankleber an den vorhergehenden Schichten (16, 20) haften;

   daß jede Polyethylenschicht (12, 24) eine Dicke von 40-100 μm hat;

   daß wenigstens eine (12) der Polyethylenschichten zur Bildung der Außenschicht eines Behälters ein Gleitmittel aufweist und einen Reibungskoeffizienten von 0,2-0,4 hat;

   daß die Kernschicht (20) ein biaxial orientiertes Polyamid mit einer Dicke von 10-40 μm aufweist;

   daß die Gassperrschicht (16) eine Dicke von 25-50 μm hat;

   und daß der Polyurethankleber ein aliphatisches Polyurethan ist;

   wobei die Schichtstruktur ausreichende Flexibilität, Festigkeit, Thermoschweißfähigkeit und Gleiteigenschaften hat, um durch Thermoschweißen auf einer Verpackungsmaschine flexible Behälter herzustellen, an denen Verschlußteile befestigt sind und die Flüssigkeit unter sterilen Bedingungen enthalten können.

2. Schichtstruktur nach Anspruch 1, wobei die Gassperrschicht (16) ein Polyvinylidenchlorid ist.

3. Schichtstruktur nach Anspruch 1 oder 2, wobei das Polyethylen ein lineares Polyethylen niedriger Dichte ist.

4. Schichtstruktur nach Anspruch 3, wobei die Dichte der linearen Polyethylenschichten niedriger Dichte 0,91-0,94 g/cm^3 ist.

5. Schichtstruktur nach Anspruch 3 oder 4, wobei die linearen Polyethylenschichten niedriger Dichte die folgenden Zusatzstoffe aufweisen:

   ein Antioxidans;
   einen Stabilisator;
   ein Gleitmittel; und
   ein Anti-Blockmittel.

6. Schichtstruktur nach Anspruch 5, wobei:

   das Antioxidans Tetrakis[methylen-3-(3'5'-di-tert.-butyl-4'-hydroxyphenyl)propionat]-methan, n-Octadecyl-beta(4'-hydroxy-3',5'-di-tert.-butylphenyl)propionat, 2,6-Di-tert.-butyl-p-kresol, Tetrakis(2,4-di-tert.-butylphenyl)-4,4'-biphenylendiphosphonit oder 1,3,5-Trimethyl-2,4,6-tris[3,5-di-tert.-butyl-4-hydroxybenzyl]-benzol;

   der Stabilisator Calciumstearat; und

   das Anti-Blockmittel Magnesiumhydroxid, Aluminiumhydroxid oder Magnesiumsilicat ist.

7. Schichtstruktur nach einem der vorhergehenden Ansprüche, wobei das Polyethylen 2-10 Gew.-% 1-Hexen als Comonomer enthält.

8. Schichtstruktur nach einem der vorhergehenden Ansprüche, wobei der aliphatische Polyurethankleber eine Dicke von 1-10 μm hat.

9. Schichtstruktur nach Anspruch 8, wobei der Polyurethankleber ein Polyester-Urethandiolharz aufweist.

10. Schichtstruktur nach einem der vorhergehenden Ansprüche, wobei die Haftfestigkeit der Polyethylenschichten (12, 24) an der Gassperrschicht (16) und der Kernschicht (20) wenigstens 1,93 N/cm (500 gms/inch) der Ablösekraft beträgt.

11. Schichtstruktur nach einem der vorhergehenden Ansprüche, wobei die Dicke der Schichtstruktur 155-230 μm beträgt.

12. Schichtstruktur nach einem der vorhergehenden Ansprüche, wobei die zweite Polyethylenschicht (12) 0,03-0,15 Gew.-% eines 8-22 Kohlenstoffatome enthaltenden Fettsäureamids aufweist.

13. Schichtstruktur nach Anspruch 12, wobei das Fettsäureamid ein Oleinsäureamid ist.

14. Flexibler Behälter, der unter sterilen Bedingungen ein Fluid oder einen Feststoff enthalten kann, der bei Temperaturen über 0 °C zu lagern ist, und der einen Körper mit den Behälter bildenden, einander gegenüberliegenden, umfangsmäßig verschweißten Wänden aufweist, die aus einer Schichtstruktur nach einem der Ansprüche 1-13 gebildet sind, wobei Teile einer Polyethylenschicht (24) zur Bildung der Wände des flexiblen Behälters miteinander thermoverschweißt sind und ein Verschlußteil (32) mit dem Körper thermoverschweißt ist.

15. Flexibler Behälter, der unter sterilen Bedingungen eine medizinische Flüssigkeit bei Temperaturen über 0 °C oder eine gefrorene medizinische Flüssigkeit enthält, wobei der Behälter einen aus einer Schichtstruktur thermogeschweißten Körper und ein mit dem Körper thermoverschweißtes Verschlußteil aufweist und wobei die Schichtstruktur keine Chemikalien enthält, die durch die Flüssigkeit extrahierbar sind, und eine Glasübergangstemperatur unter -25 °C hat, wobei die Schichtstruktur nach einem der Ansprüche 1-13 ausgebildet ist.

FIG. 1

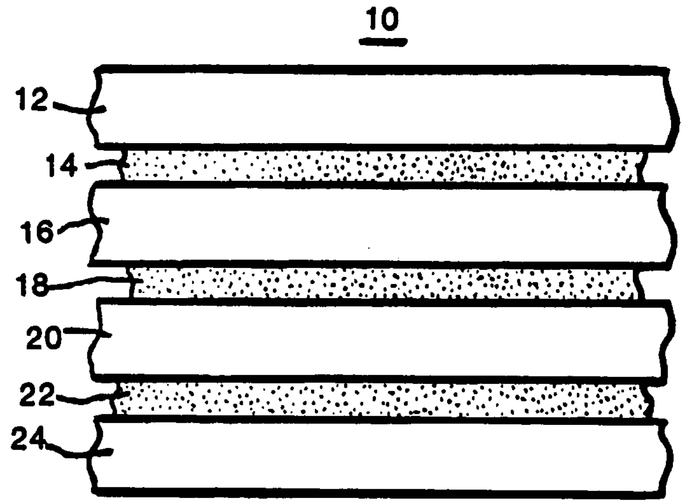

FIG. 2